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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,055	10/13/2000	Mark R. Holl		1283

23713 7590 02/04/2003

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5370 MANHATTAN CIRCLE
SUITE 201
BOULDER, CO 80303

EXAMINER

BEX, PATRICIA K

ART UNIT

PAPER NUMBER

1743

8

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/688,055	HOLL ET AL.	
	Examiner	Art Unit	
	P. Kathryn Bex	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 February 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 172-220 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 172-220 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3,5</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 172-220 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a convoluted sample storage channel fabricated from substantially rigid material, (e.g. cellulose acetate, polycarbonate, methylmethacrylate and polyester), does not reasonably provide enablement for a “non-porous” sample storage channel. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. The specification does not define the pore diameters of any of the rigid plastics disclosed, therefore the specification does not provide enablement for a “non-porous” sample storage channel.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

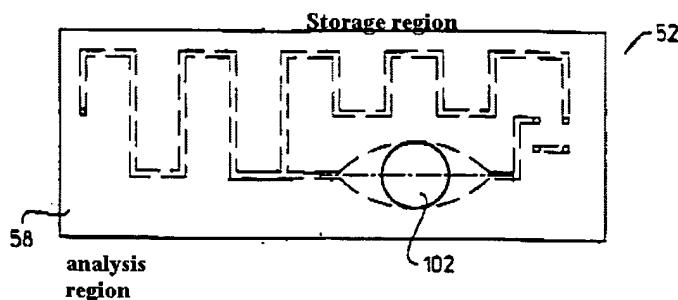
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 172-180, 182-183, 185-188, 195-198, 201, 203-208, 210-214, 217, 219-220 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaltenbach *et al* (WO 96/12546).

Kaltenbach *et al* teach a transparent fluidic sample analysis cartridge 2, 52 for use in

liquid phase separations. The cartridge comprising: a sample inlet 22 having a inlet shut-off interface (page 21) and a convoluted, isotropic, spatially periodic sample storage channel 10, 66, having particle capture regions. The cartridge includes vent (e.g. outlet 24, 78) in gaseous communication with an analysis channel. The storage channel is formed from a three-layer laminate (page 9). Additionally, Kaltenbach *et al* teach first and second analysis regions which can provide access to optical or electrical detection means (page 11, lines 7-8). The analysis regions being in fluidic connection with the storage channel. Additionally, Kaltenbach *et al* teach an analysis valve 106 positioned between storage channel and the first analysis region, see modified Figure 3 which has been labeled by the Examiner to clearly indicate the analysis and storage regions. Kaltenbach *et al* teach a reagent inlet 34 connected to reagent reservoir compartment 16, 68 with mixing channel 72 formed between the reservoir and analysis region (page 21, 2nd paragraph). Fluid flow from the reservoir can be displaced via a resuspension (e.g. diaphragm-type micropump) (paragraph bridging page 23-24, Fig. 5) The system includes a post-column collection device 752 (e.g. waste storage container) which can the sample receiving means can be one or more bibulous (e.g. absorbent or expandable) sheet means 756 for solid-phase sample collection as shown in FIG. 31.



F/G. 3

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 181,184, 199-200, 202, 215 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaltenbach *et al* (WO 96/12546).

Kaltenbach *et al* as previously discussed above, do teach the a rotating manifold for controlling the introduction of sample into the cartridge. Similarly Kaltenbach *et al* do teach a diaphragm-type pump. However, Kaltenbach *et al* do not disclose the specific use of a pinch valve or syringe pump. The use of pinch, check, poppet or squeeze valves are well known for their use in the volumetric fluid transfer art. The use of syringe and diaphragm pumps are well known for their use in the volumetric fluid transfer art. Moreover, the selection of any of these known equivalents to control fluid flow would be within the level of ordinary skill in the art.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have modified the sample analysis system of Kaltenbach *et al* within the

pinch valve, since it is well known in the art that pinch valves provide reliable fluid control without the need for complicated moving parts.

Kaltenbach *et al* discloses the claimed invention except for the shape of the mixing channel being isotropic and spatially periodic. It would have been an obvious matter of design choice to have made the mixing channel of Kaltenbach *et al* isotropic and spatially periodic in order to provide reagents which are mixed and equally distributed to the analysis channel.

8. Claims 189-194 and 209 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaltenbach *et al* (WO 96/12546) in view of Altendorf *et al* (USP 5,726,751).

Kaltenbach *et al* as previously discussed above, do not teach a cartridge with alignment marking and a holder with corresponding alignment markings. However, the use of alignment markings on both the cartridge and cartridge holder is well known in the art, see Altendorf *et al*. Altendorf *et al* teach a silicon microchannel optical flow cytometer instrument comprising a sample fluid which is hydrodynamically focused by converging sheath fluid around the sample in order to reduce channel clogging. Additionally, Altendorf *et al* teach a cartridge holder 30 for engaging a flow module, or cartridge 10 via clamps 33. The instrument having a flow cytometric measuring device optically coupled to a first analysis region of the flow module. The flow cytometric measuring apparatus having a light source and a first 120 and second 130 photodetector aligned to collected scattered or fluorescent light from the first analysis region. The cartridge having a pump interface 14 and the instrument having a syringe pump (column 5, lines 57-58). Moreover, Altendorf *et al* teach a cartridge comprising cartridge alignment markings and the optical head which includes a kinematic mount with contact elements. The cartridge can be connected to the kinematic mount (column 5, line 42- column 6, line 40).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the apparatus of Kaltenbach *et al* the alignment markings as taught by Altendorf *et al*, in order to ensure the optical head and cartridge are properly aligned without the need for extensive calibration.

9. Claim 216 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaltenbach *et al* (WO 96/12546) in view of Miyake *et al* (USP 5,736,100).

Kaltenbach *et al* as previously discussed above, do a resuspension pump. However, do not specifically recite the resuspension pump comprising an ultrasonic vibrator acoustically coupled to the reservoir. Miyake *et al* teach do teach a resuspension means comprising an ultrasonic vibrator 103 acoustically coupled to the reservoir 301 (column 1-2, Fig. 2-3).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the apparatus of Kaltenbach *et al* the ultrasonic vibrator acoustically coupled to the reservoir, as taught by Miyake *et al*, in order reduce the possibility of external contamination by the introduction of an invasive stirring mechanism.

10. Claim 218 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaltenbach *et al* (WO 96/12546) in view of Zanzucchi *et al* (USP 5,755,942).

Kaltenbach *et al* as previously discussed above, do a resuspension pump. However, do not specifically recite the resuspension pump comprising an ultrasonic vibrator acoustically coupled to the reservoir. Zanzucchi *et al* teach do teach a resuspension means comprising a stir bar (e.g. paramagnetic particles) (column 8, lines 20-27, Fig. 2-3).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the apparatus of Kaltenbach *et al* the stirring

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mechanism, as taught by Zanzucchi *et al*, in order to provide reliable and cheap means of stirring the contents of the reservoir.

Conclusion

11. No claims allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex
P. Kathryn Bex
Patent Examiner
AU 1743
January 24, 2003

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